

REMARKS

Claims 1-13 are pending in this application. New claims 14-21 are added herein. Upon entry of these claim amendments, claims 1-21 are pending in this application.

As to new claims 15, 17, 19, and 21, these claims specify that the recombinase is comprised of FLP, and the corresponding recombinase target site is comprised of frt (also designated, at times, as FRT). This recombinase/target site combination is disclosed on page 15, line 13, page 16, line 28, page 26, line 13, page 27, line 17 (citing a Science article by O’Gorman et al., which is incorporated by reference (see page 18, lines 23-25)), and page 29, line 10. As additional support, a 37 CFR § 1.132 Declaration from Dr. Frank Graham is provided. Also, one of the attachments to this declaration provides data as to the effectiveness of the FLP/frt recombinase system compared to Cre/lox. Entry and consideration of this declaration with its attachments into the file is respectfully requested.

Claim Rejections - 35 USC § 112, second paragraph

Claims 1-6, 9, 11-13 stand rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

As to claim 1, Applicant’s copy of the originally filed claim 1, in the preamble, states, “. . . contacting a cell or introducing into a cell . . .”. This is the language indicated as preferable by the Examiner. This also is the language in claim 1 above. If for any reason the copy in the Examiner’s file differs, Applicant is agreeable to an Examiner’s amendment to change this to the preferred language, and in the alternative is willing to so amend in a subsequent Reply/amendment.

As to claim 9, the lack of antecedent basis is corrected by amendment to claim 9 herein, to indicate the first and second nucleic acid sequences, rather than plasmids.

As to claim 11, phrasing in part (c) is amended herein to clarify claim 11. It is noted that, to better present the claim, both the preamble and part (c) are amended.

As to claim 12, an “and” is amended herein to conform with proper Markush claim phrasing.

As to claim 13, this claim is amended herein to present the claim in independent form.

The above amendments are made to more clearly express the subject of the claims, do not add new matter, and do not narrow the claims.

Claim Rejections - 35 USC § 102

Claims 1-3 and 5-13 stand rejected under 35 USC § 102(b) as being anticipated by Kaleko (WO/97/25446).

The Kaleko reference states that, regarding its second polynucleotide that is used in its adenoviral vector generation, that this second polynucleotide “includes at least one adenoviral ITR which includes a terminal protein bound to the ITR, . . .” (page 6, lines 6-8, underline emphasis added). The Kaleko reference repeatedly states the association of terminal protein with an ITR of a polynucleotide construct that is involved in the generation of an adenoviral vector (see, for instance, page 7, lines 26-30; other places where terminal protein is noted can be provided upon request). Applicant has not found, nor been shown, evidence that the Kaleko reference envisions practicing its invention without the use of terminal protein.

Although the specification of present invention appreciates a benefit, for certain applications, of adding terminal protein to its core invention, no claim of the present invention comprises a terminal protein attached to or associated with an ITR on either of the nucleic acid sequences used for making infectious adenovirus, nor in kits and systems. In that Kaleko teaches the presence of a terminal protein in its invention, it cannot be properly stated that Kaleko teaches

the present invention, which does not include, and which functions without, a terminal protein. That is, given that the Kaleko reference consistently taught a terminal protein attached to an ITR in its recombination, it cannot be properly stated that the arrangement of the claimed present invention, which lacks terminal protein, was taught in the Kaleko reference.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-3 and 5-13 under 35 USC § 102(b) is respectfully requested.

Claim Rejections - 35 USC § 103

Claim 4 stands rejected under 35 USC § 103(a) as being unpatentable over Kaleko (WO/97/25446), cited above, in view of Bett et al. (Proc. Natl. Acad. Sci. USA 91:8802-8806 (1994)).

In this rejection, the Office action notes that Bett et al. “disclose vectors containing a bacterial origin, an antibiotic resistance gene for selection in bacteria, and Ad5 DNA sequences (see abstract), and discloses their wide applications for the construction of Ad vectors for use as recombinant viral vaccines and for gene therapy transfer vectors . . .”. The Office action thereafter asserts that it would have been obvious to modify the vectors of the Kaleko reference to include the above-stated limitations disclosed in Bett et al.

However, because the Kaleko reference stands for recombining vectors comprising a terminal protein attached to an ITR, and because this feature important to the Kaleko reference is not in the claims of the present invention, use of the Kaleko reference is not appropriate as the primary reference in a 35 USC § 103(a) rejection. That is, in the realm of mechanisms and associated limitations for methods and compositions regarding production of recombinant viruses, and in particular adenoviruses, the Kaleko reference’s consistent use of terminal protein teaches away from the present invention. Further, and generally in regard to combination with any reference, because the Kaleko reference does not teach its practice without terminal protein, this reference is not properly used regardless of a showing of a motivation or suggestion to combine from a different reference, because even in combination the present invention is not achieved.

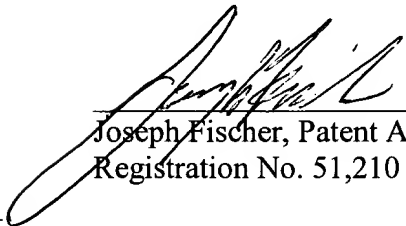
Accordingly, reconsideration and withdrawal of the rejection of claim 4 under 35 USC § 103(a) is respectfully requested.

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All claims having either been placed in condition for allowance or cancelled, expedited passage of this case to allowance is respectfully solicited.

Applicant requests that the Examiner call the undersigned if clarification is needed on any aspect of this response, or if the Examiner believes that any valid basis of non-patentability remains after entrance and consideration of the remarks and amendments presented herein. Also, the Examiner is advised of an address change and it is requested that the address recently provided for Customer Number 29847 be used henceforth.

Respectfully submitted,



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